SYSTEM FOR FIXATION OF BONE FRACTURES

DESCRIPTION

Technical Field

The present invention relates to a device for treatment of bone fractures and, more specifically to a device for improving the fixation of proximal fractures of the humerus bone.

The invention further relates to a system including at least a humeral nail to be inserted in a humeral shaft and comprising at least proximal transversal holes for the passage of corresponding locking screws, at least a screw of said locking screws having a screw head.

Background Art

As is well known in this specific orthopaedic field, proximal humeral fractures are the most common humeral fractures.

The humerus bone presents an upper part that may be considered a ball and socket joint at the shoulder. The proximal end of the humerus has an enlarged head including the ball portion. The humeral shaft extends distally away from the proximal end, toward the elbow joint.

Simple proximal humeral fractures present the humerus head or a portion of the head that is broken from the humeral shaft, often with minimal displacement.

More complex humeral fractures present two, three or four portions of the head that are broken with major displacement.

These displaced portions of the humerus head are called fragments.

The nature of the humeral fractures is generally predictable since the head tends to fracture between the ball portion and one or both tubercles of the head to which ligaments are attached. However, the reduction of a humeral fracture is still one of the most complex operation in the orthopaedic surgeony.

According to the prior art the shoulder joint may be surgically replaced by a prosthesis; however, this solution may be unsatisfactory for the patient under many points of view.

More recently, new conservative surgical techniques are gaining more and more approval for the use of a humeral nail with locking screws.

The nail is designed to be inserted in the proximal end of the humerus while the reduction and consolidation of the fragments is obtained using screws passing through proximal holes in the nail.

A nail of this kind is disclosed for instance in the German patent application No. DE 199 45 611 relating to a humeral nail having a shaft with transverse holes to hold fixing screw. Several holes in the proximal section of the shaft are offset in their height and angles to allow the screws holding the fragments in different directions.

A similar solution is also disclosed in the US patent No. 5,472,444 relating to a humeral nail having transverse holes oriented at selected angles to receive screws attached to the fragments.

When using this kind of humeral nails and locking screws it has been noted that the threaded portion of the screws tend to loose stability and overall solidity over time. In other words, the threaded portion of a screw, implanted into a corresponding fragment, looses its fastening effect since the porous bone leaves the screw free to move and rotate within the transverse hole.

This problem is even more evident in proximal humeral fractures that are particularly problematic such as those involving elderly, osteoporotic patients or in patients having cancerous tissue in the regions of the fracture.

In order to solve this further problem a prior art solution has been recently provided by using a humeral nail including at least three proximal screwholes and fully-threaded screws suitable for cancellous fixation of small bone fragments.

The bone fragments are fixed against the nail and held in place by simple locking of the screws in the screwholes. Thus, the screws are stable in the nail.

While allowing a fast proximal reconstruction of the humeral fractures, this last prior art solution still presents a serious drawback due to the fact that, after the anatomical reduction of the fractures, at least one of the screws heads remains hidden by a bone fragment, generally the lesser

tuberosity. Thus, a fast removal of this screw from the nail after consolidation is not possible and this limits a fast removal of the nail.

Moreover, even when using a fully-threaded screw the problem encountered with osteoporotic patients are not totally solved since the fragments are pulled toward the nail but inside a osteoporotic bone the threaded portion of the screw doesn't offer the required stability to forbid the rotation of the screw and its release from the corresponding screwhole.

A further drawback is that the screws cannot be inserted in any possible direction but are compelled to lie just in the direction transversal to the nail and that is not always the optimal direction to fasten all possible fragments.

A further prior art document, the US patent No. 3,709,218, discloses an intermediate plate element 28 which is inserted between a screw head 39 and the bone cortex surface. This intermediate plate 28 is bent to adhere to the bone cortex surface.

However, the shape of this intermediate plate doesn't allow to use it for the fixation of proximal fractures of the humerus bone.

A similar solution is disclosed also in the German Utility Model No. DE 89 07 443 U, but the intermediate element 12 of this document doesn't allow to enlarge the abutting surface of the locking screw head against the bone cortex.

The object of the present invention is that of providing a new fixation system for improving the fixation of proximal fractures of the humerus, even in osteoporotic bones, without the drawbacks affecting the prior art solutions.

A further object of the present invention is that of allowing fixation and consolidation of proximal fractures of the humerus through fastening means that are easy to use during the surgeony operation.

Another object of the present invention is that of reducing the stress on osteoporotic bone fragments while providing a stronger fastening action of such fragments.

Another object of the present invention in that of allowing the surgeon to fix together multiple fragments with a smaller incision of the muscle surrounding the bone.

Disclosure of Invention

According to a first embodiment of the present invention a new fixation system is provided including at least a humeral nail to be inserted in a humeral shaft and comprising at least proximal transversal holes for the passage of corresponding locking screws, at least a screw of said locking screws having a screw head; the system further including at least an intermediate plate element inserted between said screw head and the bone cortex surface so that the head is abutting against said plate.

This solution allows to enlarge the abutting surface of the locking screw head against the bone cortex thus allowing a stronger fastening action and avoiding a rotation of the screw.

Advantageously, said intermediate plate element includes a slightly curved surface to adhere substantially to the bone cortex surface.

Moreover, said intermediate plate element comprises a couple of elongated arm portions that are inserted in an astride position on the screw rod before the final fastening of the screw head.

Said intermediate plate element comprises an enlarged portion having at least a seat for embracing at least a fragment fixation pin. In a preferred embodiment said seat is at least hole formed in said enlarged portion of the plate.

Brief Description of Drawings

Figure 1 is a side and partially sectional view of a preferred embodiment of a fixation system according the present invention;

Figure 2 is a top view of the fixation system of Figure 1;

Figure 3 is a further side and partially sectional view of a further embodiment of the present invention;

Figure 4 is a top view of the fixation system of Figure 3;

Figure 5 is a perspective view of particular fastening device to be used in the fixation system according to the present invention;

Figures 6 and 7 show front and side views of the fastening device of Figure 5, respectively;

Figures 8 and 9 show respective front views of further embodiments of the fastening device of Figure 5;

Figure 10 shows a particular of a humeral nail and corresponding locking screw of the inventive fixation system;

Figures 11 and 12 shows side and a cross sectional views of the particular of Figure 10 in different working conditions, respectively;

Figure 13 is a perspective and partially cross-sectional view of the particular of Figure 10;

Figure 14 is a further perspective view of a particular of the fixation system according to the present invention.

Figure 15 is an enlarged view of the profile of the threaded portion of a screw shown in Figure 13.

Modes for Carrying Out the Invention

With reference to the drawings figures, a system for improving the fixation of proximal fractures of the humerus is globally shown at 1.

This system 1 includes an inventive fastening device 2 for fixing the locking screw or screws in their final fastening position.

The fixation system 1 of the present invention comprises a humeral nail 10 that is directly inserted in the humeral shaft 9. The nail 10 is cannulated and is inserted into the medullar bone cavity 8.

The nail 10 may be either cylindrical for all its length or have a conically tapered end portion. So, the nail 10 may have a constant or varying circular cross section throughout its length or may even present a curved portion; the form and length of the nail is not a limiting aspect of the inventive system.

The distal portion of the nail 10 presents a closed end 11 having a hemispherical form and forming a so-called "nose" of the nail.

Distal and transverse holes are provided in the distal portion of the nail 10 to receive locking screws. For instance, as shown in Figure 1, a couple of holes 12, 13 receive corresponding locking screws 32, 33 for securing the nail 10 once is has been inserted into the humeral shaft 9.

According to a first embodiment of the present invention the fixation system 1 includes the humeral nail 10, proximal locking screws 3 and at least one fastening device 2.

The humeral nail 10 includes a group of proximal transversal holes for

corresponding locking screws 3. In this embodiment at least three transversal holes 5, 6, 7 are provided in the proximal portion of the humeral nail 10.

More specifically, since the humeral nail 10 is cannulated, each of the transversal holes 5, 6, 7 comprises a couple of holes that are realised in opposite walls of the nail and that may be axially aligned. For disclosure purposes we will consider these opposite holes as a single transversal hole.

Each of the transverse holes may be oriented at a selected angle with respect to the nail longitudinal axis; however, at least two holes 5, 6 of said group of proximal holes lie on a same plane while a third screw lies in a sagittal plane.

Advantageously, the locking screws 3 are fully-threaded and present a working head 4 and an opposite rounded end 34. The working head 4 has a recessed shaped seat 29 to receive a working key, not shown and used by the surgeon.

The form of the screw's thread will be detailed disclosed hereinafter; however, it must be noted that any specific shape and thread of the screws 3 may be used in the fixation system 1 according to the invention.

As above mentioned, at least one of the locking screws 3 has a corresponding screw head 4 that, according to the prior art, would normally abut against the nail 10 or against the cortex 14 of the humeral bone.

On the contrary, according to the system of the present invention the fastening device 2 is interposed between the screw head 4 and the bone cortex surface 14. More specifically, said fastening device 2 comprises at least an intermediate plate element 15 that is inserted between said screw head 4 and the bone cortex surface 14.

Thus, when the screw 3 is totally fastened, the screw head 4 abuts against the intermediate plate element 15 instead of against the bone cortex 14.

This solution allows the enlargement of the abutting surface of the locking screw head 4 against the bone cortex surface 14, thus allowing a stronger fastening action and avoiding a further rotation of the screw 3. Moreover, this solution allows the surgeon to fix together multiple fragments with a

smaller cut.

Advantageously, said intermediate plate element 15 includes a slightly curved surface 16 to adhere perfectly to the bone cortex 14 surface, as shown in Figures 5 and 7. In a preferred embodiment the plate element 15 is slightly bent in both main axial directions thus presenting two opposite and parallel curved surfaces 16 and 17.

Just to give some indications about the shape and dimension of the intermediate plate 15, it worth to note that the whole plate element 15 could fit inside a circle having a diameter of eighteen mm and the plate thickness is of about 1 mm.

The intermediate plate 15 and the screw 3 are made by surgical steel, for instance .....??? As an alternative, they may be realised in Titanium or in a Titanium alloy.

As a possible alternative the plate 15 may be realised by a plastic material, for instance....???

Moreover, the intermediate plate element 15 has a substantially rounded profile and comprises a couple of elongated arm portions 18, 19 that are inserted in an astride position on the screw rod just before a final fastening action on the screw head 4.

Each of said arm portions 18, 19 presents a rounded end 18a, 19a.

Said intermediate plate element 15 comprises an enlarged portion 21 having at least a seat 22, as shown in Figure 9, for embracing at least a fragment fixation pin 23 to be inserted into the bone, as shown in Figures 1 and 2.

In a preferred embodiment said seat 22 is a hole 24 formed in said enlarged portion 21 of the intermediate plate 15. This hole 24 may have for instance a diameter of 2,5 mm.

In a preferred embodiment, at least two holes 24 are provided in said enlarged portion 21 and in alignment with each corresponding arm portion 18, 19, as shown in Figure 6.

In a further embodiment of the present invention one of the holes 24 may be provided close to the end of one of the arm portions 18 or 19, as shown in Figure 8.

According to the previous description the intermediate plate element 15 may be considered an open washer integrally formed with a flange portion 21.

The fragment fixation pin 23 is a thin rod 26, made of surgical steel, having a final threaded portion 25. The rod may have a diameter of 3mm while the threaded portion of the rod may have an outside diameter less than 2,5 mm.

[**Note:** the drawings show little round washers around the fixation pin but they don't need to be used since the diameter of rod is larger than the diameter of the hole 24, so the rod may be cut just above the threaded portion and kept in place without a washer]

This fragment fixation pin is disclosed in the European Patent No. 0 642 323 in the name of the same applicant and shown schematically in Figure 14.

After the surgeon has produced an anterior opening in the deltoid muscle to reach the fractured epiphyseal mass, a short incision is made in line with the deltoid fibers. Then, the deltoid fibers are divided to access to the fractured area and to the corresponding ematoma.

The nail 10 is inserted into the axis of the humeral shaft 9 and kept in place by the distal screws 32, 33. Then the fractures of the humeral head may be reduced by fixing the fragments against the humeral nail 10.

Using specific tools, the bone fragments (lesser tuberosity, greater tuberosity, humeral head, etc...) once positioned, are precision drilled before receiving the screws 3.

The screws are locked and just before the final fastening of the screw the intermediate plate 15 between the screw head 4 and the bone cortex 14 in an astride position on the screw body. It worth to note that a very small incision of the deltoid muscle, for instance 4 cm, is required to insert the plate 15 and this aids healing.

When the intermediate plate element 15 is put into its final position and the screw 3 is fastened so that the screw head 4 abuts against the plate 15 then the fragment fixation pin 23 may be inserted in the bone through

the hole 24.

The fragment fixation pin 23 may be inserted in the bone drilling a hole through the bone small enough to firmly engage the pin threads.

Advantageously, the fixation pins 23 may be oriented according to the needs of engagement of other possible fragments of the humeral head since the diameter of its threaded portion is a little smaller than the diameter of the hole 24.

The presence of the pin 23 has the double function to avoid displacement or rotation of the intermediate plate 15 and, in case of need, to fix a fragment of the humeral head.

According to a preferred embodiment of the invention a couple of fragment fixation pins 23 are inserted in the bone through the corresponding holes 24 of a plate 15 shaped as in the example of Figure 5 or 8.

However, as previously mentioned, even one fixation pin 23 may be enough for the purpose of avoiding a displacement of the plate 15 and a plate 15 including a single hole 24 may be used.

In a further embodiment of the present invention, disclosed with reference to Figures 3 and 4, a couple of intermediate plate elements 15 may be used for fixation purposes.

Those plates 15 may even have different dimension and a second plate 15' used in cooperation with the more distal of the proximal screws 3 may be greater than the other upper plate 15.

As a further alternative, the arm portions 18 and 19 of the second and more distal intermediate plate 15' may be longer than those shown in Figure 1 as a first embodiment of the present invention.

The final orientation of the plates 15 and 15' may be different, the surgeon just needs to pay attention to the position of the holes 24 so that the fragment fixation pins 23 don't interfere with the nail 10 hidden inside the bone shaft 9, as shown in Figures 3 and 4.

Even the position of the plates 15 and 15' may in some occasion be inverted, so that the larger plate 15' may be fixed by the corresponding screw 3 in the more proximal position.

Referring now to Figures from 10, 11, 12 and 13 a further embodiment of

the present invention is disclosed.

In this embodiment a humeral nail 30 is provided with at least a proximal transversal hole 27 including an internal partially threaded portion 28, clearly shown in Figures 11 and 12. This portion 28 may be considered a portion of nut screw, but even a knurl portion could meet the purposes of the invention.

As previously noted, the humeral nail is cannulated and each transversal hole comprises a couple of holes that are realised in opposite walls of the nail and that are axially aligned.

In this embodiment it's also important to identify the two opposite holes 27', 27" that form the transversal hole 27.

Each screw 3 has an outside thread diameter smaller than the diameter of the transversal hole 27 that receives the screw and the internal threaded portion 28 doesn't interfere with the screw during the normal insertion.

In a preferred embodiment the internal threaded portion 28 is provided in the hole 27' closer to the screw head 4.

The screw 3 may be put in place and fixed according to the previous disclosure, thus with the aid of the intermediate plate 15.

In case of a undesired movement or displacement of the screw 3 after its final fastening, the internal threaded portion 28 solve the problem engaging the threaded portion of the screw 3 at least in a crest to crest fashion, as shown in Figure 12.

As previously mentioned, the screw 3 may have any specific shape and thread; however, a preferred screw structure is disclosed hereinafter.

The screw 3 comprises a screw body 31 that is fully threaded.

This threaded body has a substantially cylindrical shape with a constant diameter ending in the rounded end 34.

Figure 15 is an enlarged view of the profile of the threaded portion 5 according to the invention.

Advantageously, the threaded portion has at least a section formed with a constant pitch p, preferably a 0.45 mm pitch, and comprises threads 35 having a triangular profile in cross-section with a cusp or acute apex angle of 60°.

The facing walls of two adjacent threads form an angle α of no more than 60°.

Advantageously, the bottom portion of the threads between adjacent inner walls of the threads 35 is slightly concave and rounded, effective to ease the material flow and relieve bone stress during the screw penetration.

The radius of the bottom rounded portion is 0.5 mm.

The thread height h is 0.27 mm and it is constant along the thread profile.

This thread would allow also a conical profile to be used.

The screw 3 of this invention distributes the stress better than conventional screws. Moreover, the screw 3 of this invention shows to have a better distributed compression even in the absence of interference, that is in situations of an oversize pre-drilled hole, lysis or osteoporosis.

As a whole the system according to the present invention facilitates a fast anatomical reduction of the fracture and ensured a fast consolidation as well.

Moreover, this system requires a very small incision to be made in the muscle surrounding the bone and this aids healing.

Moreover, the use of the plate 15 allows one to fix together multiple fragments with a smaller cut.